REMARKS

Claims 70-72, 74-77, 79-80, 85, 99, 105-106, 108-111, 113-114, 119, 133, and 139-148 are pending in the application. Claims 105-106, 108-111, 113-114, 119, and 133 are withdrawn. Claim 70 has been amended. Support for the amendment to claim 70 may be found at least, e.g., at page 38, lines 24-28 and at page 42, lines 8-15. No new matter has been added.

Claim rejections under 35 U.S.C. § 102

Claims 70, 71, and 99 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by Ueda et al. (1990). More specifically, the Examiner states:

> Contrary to Applicant's assertion, the reference teaches the treatment of glomerulonephritis caused by HBV in human patients (mammals) by administering interferon-ß. (*Office Action*, at p. 3)

Applicant respectfully traverses. However, to expedite prosecution, Applicant has amended claim 70 to recite a method for treating glomerulonephritis in a mammal who is otherwise free of indications for treatment with IFN-ß, said indications selected from the group consisting of lupus or viral disease.

"To anticipate a claim, the reference must teach every element of the claim." (MPEP §2131) The reference cited by the Examiner does not teach all of the claimed limitations. In particular, Ueda et al. does not teach a method for treating glomerulonephritis in a mammal who is otherwise free of indications for treatment with IFN-ß, said indications selected from the group consisting of lupus or viral disease, as recited in Applicant's claim 70. The Examiner instead has stated that the reference teaches the treatment of glomerulonephritis caused by HBV in human patients (mammals) by administering interferon-ß (*Office Action*, at p. 3). Applicant respectfully submits that the claims are novel and requests withdrawal of the rejection under 35 U.S.C. § 102.

Claim rejections under 35 U.S.C. § 103

Claims 70-72, 74-77, 79-80, 85, and 99 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Ueda et al. (1990) in view of Pedersen et al. (U.S. Pat. No. 6,531,122). More specifically, the Examiner states:

> Contrary to Applicant's assertions . . ., Ueda et al. teaches the treatment of glomerulonephritis caused by HBV in human patients (mammals) by administering interferon-ß . . . The reference also teaches that the HBV containing patients showed improvement in proteinuria . . . . Pedersen et al. (*sic*) reference taught various forms of interferon-ß used in the invention. Therefore, one of ordinary skill in the art would have been motivated to use the methods of Ueda et al. to treat glomerulonephritis by administering modified interferon-ß . . . . (*Office Action*, at pp. 4-5).

Claims 70-72, 74-77, 79-80, 85, and 139-148 stand further rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Schwarting et al. (2001) in view of Pedersen et al. (U.S. Pat. No. 6,531,122) and Chang (U.S. Pat. No. 5,908,626). More specifically, the Examiner states:

> Schwarting et al. (2001) teaches the use of interferon-ß in the treatment of lupus nephritis in a mammal . . . Pedersen et al. teach various interferon-ß preparations . . . Chang et al. disclose interferon-ß-Fc fusion protein . . . . Therefore, it would have been prima facie obvious at the time of the invention to modify the treatment methods of Schwarting et al. to treat glomerulonephritis by administering various interferon-ß molecules . . . . (*Office Action*, at pp. 7-8).

Applicant respectfully traverses this rejection. However, to expedite prosecution, Applicant has amended claim 70 to recite a method for treating glomerulonephritis in a mammal who is otherwise free of indications for treatment with IFN-ß, said indications selected from the group consisting of lupus or viral disease. The particular combinations of references cited by the Examiner do not teach or suggest all of the claimed limitations. In particular, neither of the primary references cited by the Examiner teach a method for treating glomerulonephritis in a mammal who is otherwise free of indications for treatment with IFN-ß, said indications selected from the group consisting of lupus or viral disease, as recited in Applicant's claim 70. None of the secondary references cited by the Examiner cure this deficiency.

Further, to establish a *prima facie* case of obviousness, "a reasonable expectation of success is required." (MPEP §2143.02) Applicants respectfully submit that at the time of filing there existed no reasonable expectation of success that a method for treating glomerulonephritis in a mammal who is otherwise free of indications for treatment with IFN-ß, said indications selected from the group consisting of lupus or viral disease, comprising identifying a mammal having glomerulonephritis and administering to the mammal a therapeutically effective amount of an IFN-β therapeutic, would be effective, absent the teachings of the present specification. Ueda et al. teach amelioration of an underlying hepatitis B disease with IFN-ß. According to Ueda, "Hbe-Ag and DNA polymerase have disappeared with development Hbe-Ab (seroconversion) about six months after the end of interferon-ß administration." (*See* Abstract.) Ueda et al. further state, "[t]hen nephrotic syndrome has recovered in imcomplete (*sic*) remission after a year and a half follow-up." (*See* Abstract.) Based on the teachings of Ueda et al. in view of Pedersen et al., one skilled in the art would have no reasonable expectation of success that IFN-ß treatment of glomerulonephritis would be effective absent amelioration of an underlying hepatitis B disease.

Additionally, Ueda et al. teach away at least from the methods of Applicant's claims. The subjects of the Ueda et al. reference are hepatitis B carriers associated with nephrotic syndrome. Ueda et al. summarize, "[t]hese facts suggest that the improvement of proteinuria is associated with the decrease in HBV replication due to interferon therapy." (*See abstract.*) Thus, Ueda et al. teach away from treating glomerulonephritis in a mammal who is otherwise free of indications for treatment with IFN-ß.

Schwarting et al. (2001), similar to Ueda et al., teach treatment of an underlying lupus disease. For the same reasons set forth above for Ueda et al. in view of Pedersen et al., Applicants respectfully submit that at the time of filing there existed no reasonable expectation of success that a method for treating glomerulonephritis in a mammal who is otherwise free of indications for treatment with IFN-ß, said indications selected from the group consisting of lupus or viral disease, comprising identifying a mammal having glomerulonephritis and administering to the mammal a therapeutically effective amount of an IFN-β therapeutic, would be effective, absent the teachings of the present specification. Based on the teachings of Schwarting et al. in

view of Pedersen et al. and Chang et al., one skilled in the art would have no reasonable expectation of success that IFN-ß treatment of glomerulonephritis would be effective absent amelioration of an underlying lupus disease. Similarly, Schwarting et al. in view of Pedersen et al. and Chang et al. do not teach a method for treating glomerulonephritis in a mammal, consisting essentially of identifying a mammal having glomerulonephritis and administering to the mammal a therapeutically effective amount of an IFN-β therapeutic, as recited in claims 143-144 and 148. The subject matter of claims 143-144 and 148 is such that identifying a mammal having lupus is not required.

Additionally, Schwarting et al. teach away from the methods of Applicant's claims. The subjects treated with IFN-ß in Schwarting et al. are MRL-*Fas*^{lpr} mice. Thus, Schwarting et al. teach away from treating glomerulonephritis in a mammal who is otherwise free of indications for treatment with IFN-ß.

Applicant respectfully submits that the claims are nonobvious and requests withdrawal of the rejection under 35 U.S.C. § 103.

CONCLUSION

In view of the amendments and arguments presented above, Applicant believes the claims are in condition for allowance, which action is respectfully requested. If a telephone conversation with Applicant's Agent would expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 832-1749.

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Respectfully submitted,

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